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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,879	10/12/2005	Terrence R Langford	122123.00004US1	4467
34282	7590	05/29/2007	EXAMINER	
QUARLES & BRADY LLP ONE SOUTH CHURCH AVENUE, SUITE 1700 TUCSON, AZ 85701-1621			DELCOTTO, GREGORY R	
ART UNIT		PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	10/552,879	LANGFORD, TERRENCE R
	Examiner Gregory R. Del Cotto	Art Unit 1751

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 15 March 2007.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 14-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 14-29 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 3/15/07.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application
- 6) Other: _____.

DETAILED ACTION

1. Claims 14-29 are pending. Claims 1-13 have been canceled. Note that, the preliminary amendment filed 3/15/07 has been entered.

Objections/Rejections Withdrawn

The following objections/rejections as set forth in the Office action mailed 11/1/06 have been withdrawn:

The objection to claim 20 due to minor informalities has been withdrawn.

The rejection of claims 14-29 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The rejection of claims 21-29 are rejected under 35 U.S.C. 102(a) as being anticipated by WO02/32467 has been withdrawn.

Priority

Note that, priority has been corrected.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "substantially" in claim 14 is a relative term which renders the claim indefinite. The term "substantially" is not defined by the claim, the specification does

not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Note that, in the absence of a definition in the specification, it is unclear what is meant by "substantially" degrade. For example, does "substantially" degrade mean that there is less than 1%, 0.01%, 0.001%, etc., residue remaining on the disinfected item?? Thus, one of ordinary skill in the art would not be able to determine the metes and bounds of the claimed invention. Clarification is required. Note that, claims 15-20 have also been rejected due to their dependency on claim 14.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical

Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 14-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Langford (US 5,443,801) in view of Hitchems et al (US 6,468,953).

Langford teaches a cleansing/sterilizing apparatus which is a transportable apparatus and for inside-outside and sterilization of various complex reusable medical/dental instruments, including but not limited to laparoscopic instruments and dental handpieces. See Abstract. Specifically, Langford teaches filling a wash chamber and soaking the instruments with filtered ozonated water agitated by a

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peristaltic pump to denature any protein contaminants; draining the soak water by injecting sterile oxygen gas or sterile inert gas; washing the instruments with detergent in warm filtered water; draining the wash water by injecting sterile oxygen gas or sterile inert gas; rinsing the instruments with filtered ozonated water agitated by the peristaltic pump to sterilize all surfaces inside and out and to flush any remaining bio-debris; and draining the rinse water. The rinse cycle may be repeated multiple times. See column 21, lines 1-50.

Langford et al do not teach the specific amount of ozone in the water, the use of a chemical sterilizing agent such as peracetic acid or a method of cleaning and sterilizing a soiled item using the specific process steps including treating an item with a chemical sterilizing agent to achieve high level disinfection as recited by the instant claims.

Hitchems et al teach the formation of antimicrobial solutions formed by ozonating a liquid containing organic precursor molecules. After ozonation is complete, the ozonated liquid may be diluted with water or other solvent to form a use solution for contacting and cleaning a microbially contaminated surface or other medium. See Abstract. Additives to the solution may include antimicrobial agents such as peroxygen-type disinfectants including peracetic acid, etc. See column 11, lines 30-65. The ozonated solution has a water to a water/ozonated solution ratio of between 1 and 100. See column 4, lines 30-55.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to use water having the same volume of ozone as recited by

instant claim 17, with a reasonable expectation of success, because Hitchems et al teach the use of ozone containing liquids having the same amount of ozone as recited by the instant claims for sterilizing medical instrument surfaces and further, Langford et al teach using ozone containing liquids for sterilizing medical instruments in general.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to use an antimicrobial agent such as peracetic acid in the ozone rinse step in the process of sterilizing endoscopes taught by Langford et al, with a reasonable expectation of success, because Hitchems et al teach the use of peracetic acid as an antimicrobial agent in a similar process using ozone as a cleaning/disinfecting agent and further, the use of antimicrobial agents such as peracetic acid would be desirable because of the additional disinfection/sterilization properties provided by the use of peracetic acid in combination with ozone.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to sterilize a soiled item using the specific process steps including treating an item with a chemical sterilizing agent to achieve high level disinfection as recited by the instant claims, with a reasonable expectation of success, because the broad teachings of Langford in combination with Hitchems et al suggest sterilizing a soiled item using the specific process steps including treating an item with a chemical sterilizing agent to achieve high level disinfection as recited by the instant claims.

Claims 21-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO02/32467.

'467 teaches an apparatus for cleaning medical equipment comprising a supply of filtered water, a supply of ozonated water containing a predetermined concentration of water and means for delivering first a flow of filtered water over the surfaces of the equipment to be cleaned for a predetermined time followed by a flow of ozonated water over said surfaces for a predetermined time to disinfect the surfaces. See Abstract. The ozonated water is de-ionized prior to ozonating to the predetermined concentration. In the system, unozoneated water was pumped through the system for 10 minutes and then ozonated water was pumped through the system for 6 minutes which achieves a high level disinfection. See page 6, lines 1-15. After the cycle, rinse water and ozonated water may also be flowed over the outer surface of the endoscopes to disinfect these as well. See page 7, lines 10-35. The apparatus is comprises a means for filtering the tap water used in the process to provide a supply of filtered water. Note that, the Examiner asserts that '467 teaches high-level disinfection and that it would have been obvious to one of ordinary skill in the art to run an endoscope through two or more cycles of high-level disinfection taught by '467 on instruments contaminated with hard to kill bacteria to ensure disinfection of the instruments. This type of disinfection which employs several cycles of disinfection is well known to those skilled in the art to thoroughly sterilize medical instruments or resterilize instruments immediately before use and would suggest rinsing an already cleaned and high-level disinfected item with water following by flushing the item with ozone as recited by the instant claims.

'467 does not teach, with sufficient specificity, a method of preventing recontamination of a cleaned and high-level disinfected item comprising rinsing the

cleaned and high-level disinfected item with water following by flushing the item with ozone as recited by the instant claims.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to prevent recontamination of a cleaned and high-level disinfected item comprising rinsing the cleaned and high-level disinfected item with water following by flushing the item with ozone as recited by the instant claims, with a reasonable expectation of success, because the broad teachings of '467 suggest preventing recontamination of a cleaned and high-level disinfected item comprising rinsing the cleaned and high-level disinfected item with water following by flushing the item with ozone as recited by the instant claims.

Response to Arguments

With respect '467, Applicant states that there is no disclosure of a method in which high-level disinfected items subsequently are rinsed with water and then ozone. In response, note that the Examiner has made a new grounds of rejection, as set forth above, and maintains that '467 teaches high-level disinfection and that it would have been obvious to one of ordinary skill in the art to run an endoscope through two or more cycles of high-level disinfection taught by '467 on instruments contaminated with hard to kill bacteria to ensure disinfection of the instruments.

With respect to the rejection of the instant claims under 35 USC 103(a) over '801 in combination with Hichems et al, Applicant states that '801 does not disclose or suggest an "overkill rinse" of an already cleaned and high-level disinfected item and the Applicant submits that the repeated rinsing is to effect sterilization, not to provide a final

chemical-degrading and biomatter “overkill” rinse of first water and then ozone for an already high-level disinfected item as recited in steps e) and f) of claim 15. Additionally, Applicant states that one of ordinary skill in the art would not take the ‘801 patent’s repeated rinsing with ozonated water to suggest a separate chemical degradation and biomatter “overkill” rinse because no chemical sterilant is used in the ‘801 patent’s disclosed method. Additionally, the Applicant also submits that there would be no motivation to combine the ‘801 patent and Hitchems et al reference because the ‘801 patent specifically teaches away from the use of “corrosive chemicals”. In response, note that, the Examiner maintains that ‘801 teaches that the instruments may be rinsed with ozone and then water, followed by ozone again which suggests steps e) and f) of instant claim 14. While ‘801 may not specifically mention substantially degrading any remaining chemical residue and biomatter due to the rinse with ozone, the reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. Note that, while there must be motivation to make the claimed invention, there is no requirement that the prior art provide the same reason as the applicant to make the claimed invention. In re Linter, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972). See MPEP 2144.

Furthermore, the while Applicant states that one of ordinary skill in the art would not be motivated to use peracetic acid in the compositions taught by ‘801, the Examiner asserts that the instant claims recite no specific amount of “chemical sterilizing agent”

and that one of ordinary skill in the art would be motivated to use small amounts of peracetic acid which would not damage the apparatus of '801 in the compositions taught by '801 due to the enhanced disinfection properties provided by peracetic acid.

Additionally, Applicant states that even if one were motivated to combine the '801 patent with Hitchems et al, the rinsing steps e) and f) would still not be disclosed because the chemical sterilants of Hitchems et al would take the place of the ozone rinse for the sterilization step taught by the '801 patent. In response, note that, the Examiner asserts that peracetic acid as taught by Hitchems et al would be used in combination with ozone in the process taught by '801 and thus, peracetic acid/ozone would be used to rinse the instruments in '801 which would suggest d) of claim 14, water would be used to rinse the instruments in '801 which would suggest e) of claim 14, followed by peracetic acid/ozone in '801 which would suggest f) of claim 14.

With respect to the Declaration submitted by Applicant, the Examiner asserts that the Declaration is not sufficient to overcome the prior art rejections of record. Note that, in the Declaration, it is stated that the invention is not obvious because the claimed method has produced unexpected results with respect to the reduction of microbial loading with no colony forming units. In response, note that, this reduction of microbial loading with no colony forming units is what one of ordinary skill in the art would reasonably expect from the teachings of the prior art, and is thus not unexpected; '801 and '467 both teach the use of ozone as the disinfecting material, which is the same as recited by the instant claims, and suggest methods which apply ozone several times to the surface being disinfected. Additionally, '467 teaches that the process fulfills the

HIRL test criteria for endoscope washer disinfectors since it has a mean log reduction of greater than 6. See page 3, lines 1-10 of '467.

Additionally, as further evidence that the claims do not recite an obvious variation on the '801 patent and Hitchems et al's invention is further demonstrated by the fact that, despite the existence of numerous cleaning and sterilizing apparatus and methods for reusable items, ensuring that cleaned and sterilized items are contaminant free remains an issue as evidenced by an article from The Wall Street Journal. In response, note that, while this article does detail the fact sterility of endoscopes and other surgical instruments is a problem in the medical field, the Examiner asserts that this does not negate the fact that the prior art of record teaches the use of ozone in successive steps from high-level disinfecting of instruments as recited by the instant claims. The Examiner asserts that, despite various articles or other documentation which shows the need for better cleaning of endoscopes, the prior art of record is sufficient to render the claimed invention obvious.

Conclusion

2. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Remaining references cited but not relied upon are considered to be cumulative to or less pertinent than those relied upon or discussed above.

Applicant is reminded that any evidence to be presented in accordance with 37 CFR 1.131 or 1.132 should be submitted before final rejection in order to be considered timely.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory R. Del Cotto whose telephone number is (571) 272-1312. The examiner can normally be reached on Mon. thru Fri. from 8:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Douglas McGinty can be reached on (571) 272-1029. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Gregory R. Del Cotto
Primary Examiner
Art Unit 1751

GRD
May 23, 2007